



FH

**STATE OF WISCONSIN
Division of Hearings and Appeals**

In the Matter of

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

DECISION

MPA/173330

PRELIMINARY RECITALS

Pursuant to a petition filed April 01, 2016, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Division of Health Care Access and Accountability in regard to Medical Assistance (MA), a hearing was held on April 28, 2016, at Waukesha, Wisconsin.

The issue for determination is whether the agency properly denied the Petitioner's prior authorization request for Daklinza.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, Wisconsin 53703

By: [REDACTED]
Division of Health Care Access and Accountability
1 West Wilson Street, Room 272
P.O. Box 309
Madison, WI 53707-0309

ADMINISTRATIVE LAW JUDGE:

Debra Bursinger
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner is a resident of Waukesha County.

2. On March 7, 2016, the Petitioner's pharmacy provider, [REDACTED], submitted a prior authorization request on behalf of the Petitioner for Daklinza and Sovaldi. The request included a PA Drug Attachment for Hepatitis C Agents. It reported that Petitioner's diagnosis is Hep C genotype 3, diagnosed on August 12, 2015. It was also reported that the Petitioner has not had a liver biopsy but did have liver scans on July 14, 2015 and February, 2016. A copy of the results of the scan was not submitted. It is also noted that the Petitioner does not have cirrhosis of the liver. Also submitted with the PA request was an Exemption Request for Daklinza. It reported that the preferred treatment, Viekira Pak, is not acceptable treatment for genotype 3. No medical records were submitted with the PA request.
3. On March 14, 2016, the agency issued a notice to the Petitioner that his PA request was denied.
4. On April 1, 2016, the Petitioner filed an appeal with the Division of Hearings and Appeals. The appeal included a letter from the Petitioner's physician and medical records, including a copy of the results of the liver scans showing elevated liver enzymes. It reports that the Petitioner has elevated liver enzymes.

DISCUSSION

The Wisconsin MA program pays for some prescription drugs. Wis. Admin. Code § DHS 107.10. Clinical prior authorization for all hepatitis C agents, including preferred drugs, is required as a condition of payment. ForwardHealth Update 2015-50 (October, 2015).

In evaluating a PA request, the program considers the authorization standards at § DHS 107.02(3)(e). Those standards include the requirements that the requested service be a medical necessity, appropriate, and cost effective, and that the existence of less expensive alternative services be considered. *Id.* The petitioner bears the burden of proving that these standards are met.

As an aid to assure consistent authorization request evaluation/approval for hepatitis C drugs, the Division's consultants have implemented policy standards related to severity, which became effective in December, 2014 and were updated in March and October, 2015. The update in October, 2015 specifically addresses requests for Daklinza as a combined treatment with Sovaldi. It notes:

Daklinza™ and Technivie™, which are hepatitis C agents, require PA until further notice.

Daklinza™ and Technivie™ are non-preferred drugs and are scheduled to be reviewed by the Wisconsin Medicaid Pharmacy PA Advisory Committee as part of the PDL review in the summer of 2016 in the hepatitis C agents drug class. Until the next PDL review of this drug class has occurred, the following PA criteria have been established for Daklinza™ and Technivie™.

Prior Authorization Requests for Use of Daklinza™ as a Combined Treatment with Sovaldi™ That Will Be Considered for Review

Only PA requests for the use of Daklinza™ and Sovaldi™ as a combined treatment for members whose hepatitis C liver disease has advanced to any of the following stages may be considered for review:

- ☐ Compensated cirrhosis (i.e., CTP class A)
- ☐ Evidence of bridging fibrosis (e.g., Metavir score of F3 or greater)
- ☐ Serious extra-hepatic manifestations of HCV

In addition, only PA requests for members who have chronic hepatitis C genotype 3 infection will be considered for review.

Conditions or Circumstances for Use of Daklinza™ as a Combined Treatment with Sovaldi™ for Which Prior Authorization Requests Will Be Denied

Prior authorization requests for the use of Daklinza™ and Sovaldi™ as a combined treatment will be denied in the following circumstances:

- ☐ The member has acute hepatitis C.
- ☐ The member has a significant or uncontrolled concurrent disease (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease, thyroid disease).
- ☐ The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C). (Note: If the member is currently on a liver transplant wait list with an elevated Model for End-Stage Liver Disease [MELD] score, individual circumstances will be considered for review.)
- ☐ The member has received a liver transplant.
- ☐ The member is currently abusing drugs or alcohol.
- ☐ Members with compensated cirrhosis must be abstinent from alcohol for the six months prior to and during HCV treatment.
- ☐ Members must no longer be abusing drugs for at least six months prior to HCV treatment.
- ☐ Active participation in a recovery program is required for members with a recent history of alcohol or drug abuse.
- ☐ The member has taken a prior course of therapy with Daklinza™ or Sovaldi™.
- ☐ Non-compliance with approved hepatitis C treatment regimen.

ForwardHealth Update, 2015-504 (October, 2015).

The records submitted by the Petitioner and his provider do not demonstrate that the Petitioner's condition has not deteriorated to the levels identified in the above policy to allow approval of the PA request. He does not have cirrhosis of the liver. There is no evidence of serious extra-hepatic manifestations of the hepatitis C virus. There is no evidence of a Metavir score of F3 or greater. At the hearing, the Petitioner testified that he has a Metavir of F3; however, I found no evidence in the medical records to support his testimony. I note that a diagnosis of Hep C type 3 is not the same as having a Metavir score of F3.

Based on the evidence presented and the current policy as noted above, I must conclude that the agency properly denied the Petitioner's PA request. The evidence does not demonstrate that the Petitioner meets the criteria for approval under the policy developed by the agency for Daklinza as a combined treatment with Sovaldi.

I note that the Petitioner contacted DHA post-hearing to report that his liver enzymes remain elevated. This decision does not prevent the Petitioner from filing a new PA request at any time and submitting evidence with that request to demonstrate that he meets the criteria for coverage.

CONCLUSIONS OF LAW

The agency properly denied the Petitioner's PA request.

THEREFORE, it is

ORDERED

That the Petitioner's appeal is dismissed.

REQUEST FOR A REHEARING

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision**. Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

APPEAL TO COURT

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, Madison, Wisconsin 53703, **and** on those identified in this decision as "PARTIES IN INTEREST" **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Milwaukee,
Wisconsin, this 15th day of June, 2016

\sDebra Bursinger
Administrative Law Judge
Division of Hearings and Appeals



State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

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The preceding decision was sent to the following parties on June 15, 2016.

Division of Health Care Access and Accountability